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26191	7590	08/06/2007	EXAMINER	
FISH & RICHARDSON P.C. PO BOX 1022 MINNEAPOLIS, MN 55440-1022			BAGGOT, BRENDAN O	
		ART UNIT	PAPER NUMBER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/715,100	KODALI ET AL.
	Examiner Brendan O. Baggot	Art Unit 1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 16 May 2007.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 24-43 is/are pending in the application.  
 4a) Of the above claim(s) 42-44 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 24-41 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 26 October 2004 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>1/30/06, 6/17/04, 11/17/03</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|   | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

***Restriction / Election***

1. Applicant's election without traverse of Group I, claims 24-41 in the reply filed on 5/16/07 is acknowledged. Claims 42-44 are withdrawn from further consideration. Claim 24-41 are pending and examined in the instant application. This restriction is made FINAL.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Specification***

2. Applicant is required to update the status (pending, allowed, etc.) of all parent priority applications in the first line of the specification. The status of all citations of US filed applications in the specification should also be updated where appropriate.

***Claim Rejections - 35 U.S.C. §112, second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 24-33, 35 and 39-41 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

In Claims 24-33, 35 and 39-40, the metes and bounds of "at least about" is unclear because "at least" specifies a minimum value and "about" implies that the minimum can be less. Dependent claim 41 is similarly rejected. Appropriate correction is required in response to this Office Action.

In Claims 39-40, the metes and bounds of "less than about" is unclear because "less than" specifies a minimum value and "about" implies that the minimum can be less. Appropriate correction is required in response to this Office Action.

***Claim Rejections - 35 USC § 112, 1<sup>st</sup>, paragraph, written description***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 24-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to a method of making any Brassica plant species/seeds.

Applicants describe *Brassica napus* plants and seeds.

Applicants do not describe a method of making any *Brassica* plant species/seeds.

Applicants fail to describe a representative number of *Brassica* species/seeds which are required to practice said method. Furthermore, Applicants fail to describe structural features common to members of the claimed genus of any *Brassica* plant species/seeds with said oil content. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Furthermore, given the lack of description of the necessary elements essential for any *Brassica* plant species/seeds with said oil content, it remains unclear what features identify any *Brassica* plant species/seeds with said oil content. Since the genus of any *Brassica* plant species/seeds has not been described by specific structural features, the specification fails to provide an adequate written description to support the breadth of the claims.

The Applicant has not adequately described the starting materials. Applicant claims a method of making any plant with 82% monounsaturated fatty acids (MUFA) by crossing any 1<sup>st</sup> plant with greater than or equal to 45% erucic acid with any 2<sup>nd</sup> plant with at least about 84% oleic acid. It is well known in the art that not all plants can be successfully crossed to just any plant. Applicant seeks to exclude others from crossing any said plants, but the fact is that some of said plants simply can not be crossed with some other of said plants. Moreover, even among *Brassica* species, successfully crossing some species with others is known to be essentially impossible.

See *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1562, 19 USPQ2d 1111, 1115

(Fed. Cir. 1991). It is the purpose of warning an innocent purchaser, or other person using a machine, of his infringement of the patent; and at the same time, of taking from the inventor the means of practicing upon the credulity or the fears of other persons, by pretending that his invention is more than what it really is, or different from its ostensible objects, that the patentee is required to distinguish his invention in his specification.

The Federal Circuit has clarified the application of the written description requirement.

The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997); See also *Fiddes v. Baird*, 30 USPQ2d 1481 (Bd. Pat. App. & Int. 1993). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id. Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." Id.

Finally, the court held:

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. Id.

See also MPEP Section 2163, page 174 of Chapter 2100 of the August 2005 version, column 1, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

See also *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus of sequences as broadly claimed. Given the lack of written description of the claimed genus of sequences, any method of using them, such as transforming plant cells and plants therewith, and the resultant products including the claimed transformed plant cells and plants containing the genus of sequences, would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of the claimed invention at the time of filing. See The Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111.

***Claim Rejections - 35 U.S.C. §112, first paragraph, enablement***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 24-41 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of using the taught lines, does not reasonably provide enablement for any deposited cultivar lines. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Applicant would need to have a deposit of any deposited cultivar lines.

6. Claims 24-41 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of making Brassica napus plants/seeds, does not reasonably provide enablement for a method of making any Brassica plants/seeds. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The Wands court set forth the enablement balancing test:

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Wands states at page 1404, "Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior

art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the 'claims.'

The claims are broadly drawn to a method of making *any* *Brassica* plant.

Applicants teach a method of making *Brassica napus* plant species/seeds.

Applicants do not teach a method of making any *Brassica* plant species/seeds.

Applicants have not adequately taught the starting materials. Applicant claims a method of making any plant with 82% monounsaturated fatty acids (MUFA) by crossing any 1<sup>st</sup> plant with greater than or equal to 45% erucic acid with any 2<sup>nd</sup> plant with at least about 84% oleic acid. It is well known in the art that not all plants can be successfully crossed to just any plant to produce the claimed product of the method.

The state-of-the-art is such that one of skill in the art cannot predict whether *any* *Brassica* plant species seeds could be produced by the claimed method.

Despite successfully transferring genes from *B. napus* or *B. campestris* to *B. oleracea*, Quazzi et al teaches (1988) Interspecific hybrids between *Brassica napus* L. and *B. oleracea* L. developed by embryo culture. Theor. Appl. Genet. 75: 309-318) that "[I]nterspecific hybrids between *Brassica napus* and *B. oleracea* are difficult to produce, and previous attempts to transfer economic characters from one species to the other have largely been unsuccessful."

The specification has no working examples of a method of making any *Brassica* plant species/seeds. The specification does have working examples of a method of making *Brassica napus* plants/seeds.

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In the instant case, along with the absence of working examples, the relatively small amount of guidance in the specification, the unpredictability in the art and the large amount of experimentation would be necessary to achieve function balanced only against the high skill level in the art, it is concluded that it would require undue experimentation for one of skill in the art to perform the method of the claim as broadly written.

7. Claims 24-41 require the use of particular cultivars, namely any plant. The specification does not provide any guidance regarding the composition of said cultivar, the location of the deposit of the cultivar, or any guidance regarding any particular culturing, growing, or employing methods. Accordingly, one skilled in the art would not know how to make and/or use said cultivars.

The invention appears to employ novel cultivars. Since the cultivar is essential to the claimed invention it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the cultivar is not so obtainable or available, the requirements of 35 USC 112 may be satisfied by a deposit of the cultivar. The specification does not disclose a repeatable process to obtain the cultivar, and it is not apparent if the cultivar is readily available to the public. Thus, a deposit is required for enablement purpose. If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance

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of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

- (a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;
- (d) a test of the viability of the biological material at the time of deposit (see 37 CFR 1.807); and,
- (e) the deposit will be replaced if it should ever become inviable.

Applicant's attention is directed to M.P.E.P. §2400 in general, and specifically to §2411.05, as well as to 37 C.F.R. § 1.809(d), wherein it is set forth that "the specification shall contain the accession number for the deposit, the date of the deposit, the name and address of the permit examination." The specification should be amended to include this information, however, Applicant is cautioned to avoid the entry of new matter into the specification by adding any other information.

#### ***Claim Rejections - 35 U.S.C. §103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to

a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

35 U.S.C. §103(a).

The *Graham* court set forth the factual inquiries that are applied for determining obviousness under 35 U.S.C. 103(a):

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

*Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966).

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 24-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong (5,638,637-US, 24 November 1998) in view McVetty (1996) *Can. J. Plant Sci.* 76:343-344.) and further in view of Downey (1963) *Can. J. Plant Sci.* 43:271-275), and in light of (Siebel, TAG 77:489-494).

Wong teaches or suggests a method of making a plant producing seeds, said method comprising the steps of crossing plant(s) of a first plant line with plant(s) of a

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second plant line and selecting progeny (col. 7, line(s) 10-50) of said cross that produce seeds having a long chain monounsaturated fatty acid content of at least about 82% (col. 9 @ the bottom table) with erucic acid content of at least about .06% based on total fatty acid composition, wherein seeds of said first plant line have an erucic acid content of at least about .06% based on total fatty acid composition and seeds of said second plant line have an oleic acid content of at least about 84% based on total fatty acid composition.

Wong does not teach an erucic acid content of at least about 15%

McVetty teaches cultivars Neptune and Hero, both *Brassica napus* L., which are high erucic acid (50.0% or greater) rapeseed lines. (*Id.* @ page 343, Table 1).

Downey (1963) Can. J. Plant Sci. 43:271-275) teaches methods of breeding for oil quality in rape (*B. napus*), that variations in oil are of interest to the oil industry, and that extremes of variability in erucic acid were obtained from two varieties of *B. napus*.

Downey started with a zero-erucic acid parent (Lih) and a 40% erucic acid parent (Golden). Downy reports that when both lines were selfed, the offspring were the same as the parent, but when a zero-erucic acid line was crossed with high erucic acid line, the oil from the F2 seeds was intermediate in erucic acid content. (Downey @ page 273).

Seibel teaches that the levels of erucic acid can be fixed at a large number of values ranging from 1-60% and that high erucic acid oils can be used as feedstock for chemical industries and are excellent lubricants. (Seibel, TAG 77:489-494, particularly page 489).

The ordinarily skilled artisan would recognize that the limitations of claims 32-40 would inherently be met by a method of making a plant producing seeds with a cross of Hero x Wong or a cross of Neptune x Wong.

Motivation can be found in Wong's teaching or suggestion that the trait can be transferred through conventional breeding. (Wong @ col. 7, line(s) 10-17). Wong also teaches that "once established the desired traits can be transferred between . . . species using the same conventional plant breeding techniques involving pollen transfer and selection. Wong also teaches that the transfer of other traits such as low erucic acid content by standard plant breeding techniques is well documented." (Wong @ col. 7). Motivation can also be found in Wong's teaching or suggestion that monounsaturated fatty acids are a valuable dietary constituent, that in recent years studies have established the value of monounsaturated fatty acids, and that a diet high in oleic acid is thought to avoid the problem of arteriosclerosis that results from saturated fatty acids. (Wong @ col. 2).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use the prior art high erucic acid line of Hero or of Neptune in a cross with the high oleic acid line of Wong for the purposes of producing a variety of oil containing rapeseeds containing a range of both oleic acid and erucic acid.

One skilled in the art would have been motivated to generate the claimed invention because both oils have commercial value as taught by Wong and Seibel.

One would have had a reasonable expectation of success because methods of breeding for oil quality in rape were known in the art and because desired traits can be

transferred using conventional plant breeding techniques as taught by Wong. Furthermore, it was known in the art that the levels of erucic acid can be fixed at a large number of values ranging from 1-60%. Accordingly, one of ordinary skill in the art would have generated the claimed invention.

### **Conclusion**

#### **9. All Claims are rejected.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brendan O. Baggot whose telephone number is 571/272-5265. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571/272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**DAVID H. KRUSE, PH.D.**

**PRIMARY EXAMINER**



bob